Supplement to

INFORMATION LETTER

NATIONAL CANNERS ASSOCIATION

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FDA REGULATION UNDER FOOD ADDITIVE LAW

(from Federal Register of March 17)

The FDA published in the Federal Register of March 17 an order extending the time during which certain can lining ingredients may be used. The order authorizes continued use of can lining ingredients comprising all categories of materials entering into lining formulations, insofar as they may be food additives, on the ground that no imminent risk to health is involved and that additional time is needed to appraise the entire list. Also involved is the consideration that a minimum quantity of any of the materials will be imparted to food, consistent with good manufacturing practices.

A few materials listed in the request for extension of time were not included in the regulation just published, because further study is needed to determine whether they are characterized accurately enough for decisions to be reached.

Following is the text of the FDA order.

Title 21—FOOD AND DRUGS

Chapter I—Food and Drug Administration, Department of Health, Education, and Welfare

SUBCHAPTER B—FOOD AND FOOD PRODUCTS

PART 121—FOOD ADDITIVES

Subpart A—Definitions and Procedural and Interpretative Regulations

SUBSTANCES MIGRATING TO FOOD FROM LININGS OF CONTAINERS USED IN FOOD PACKAGING

The Commissioner of Food and Drugs, pursuant to authority provided in the Federal Food, Drug, and Cosmetic Act (sec. 6(c), Public Law 85-929; 72 Stat. 1788; 21 U.S.C., note under sec. 342) and delegated to him by the Secretary of Health, Education, and Welfare (23 F.R. 9500) hereby authorizes the use in foods of certain additives for which tolerances have not yet been established or petitions therefor denied. *It is ordered*, That the food additive regulations (24 F.R. 2434, 25 F.R. 1727, 1772) be amended by inserting in § 121.87 the following new paragraph (d):

§ 121.87 Extension of effective date of statute for certain specified food additives as indirect additives to food.

On the basis of data supplied in accordance with § 121.85 and findings that no undue risk to the public health is involved and that conditions exist that make necessary the prescribing of an additional period of time for obtaining tolerances or denials of tolerances or for granting exemptions from tolerances, the following additives may be used in connection with the production, packaging, and storage of food products, under certain specified conditions, for a period of 1 year from March 6, 1960, or until regulations shall have been issued in accordance with section 409 of the act, whichever occurs first. The extensions are granted under the condition that a minimum quantity of the additive will be incorporated in the food, consistent with good manufacturing practice.

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(d) *Substances migrating from linings of containers used in food packaging.* In addition to the requirements set forth in the introduction to this section, the following additives may be used in linings of containers used in food packaging under the condition that a minimum quantity of the additive from the linings will be incorporated in the food, consistent with good manufacturing practice. While preliminary data show that many of the substances included in the list may not migrate to foods, these are being included pending the completion of additional scientific work involving them.

(1) Drying oils, including the triglycerides or fatty acids derived therefrom:

Chinawood.
Castor (including dehydrated).
Tall.
Linseed.
Oiticica.
Beechnut.
Candlenut.
Coconut.
Corn.
Cottonseed.
Fish (refined).
Hempseed.
Perilla.
Poppyseed.
Pumpkinseed.
Safflower.
Sesame.
Soybean.
Sunflower.
Walnut.

The oils may be raw, heat-bodied, or blown. They may be refined by filtration, degumming, acid or alkali washing, bleaching, distillation, partial dehydration, partial polymerization, or solvent extraction or modified by combination with maleic anhydride.

(2) Reconstituted oils from triglycerides or fatty acids derived from the oils listed in subparagraph (1) of this paragraph to form esters of:

Ethylene glycol.
Pentaerythritol.
Polyethylene glycol.
Polypropylene glycol.
Propylene glycol.
Sorbitol.
Trimethylol ethane.
Trimethylol propane.

(3) Synthetic drying oils:

Butadiene styrene copolymer.
Polybutadiene.

(4) Natural fossil resins:

Copal.
Damar.
Elemi.
Gilsonite.
Glycerol ester of damar, copal, elemi, and sandarac.
Minyak.
Sandarac.
Shellac.
Utah coal resin.

(5) Rosin derivatives, including modification by polymerization, isomerization, decarboxylation, and hydrogenation, and methyl ester of hydrogenated rosin:

Rosin esters:
Bisphenol-epichlorohydrin (epoxy).
Diethylene glycol.
Ethylene glycol.
Glycerol.
Methanol.
Pentaerythritol.
Rosin esters modified by reaction with:
Maleic anhydride.
Ortho-, meta-, and para-substituted phenol-formaldehyde as listed in subparagraph (6) of this paragraph.
Phenol-formaldehyde.
Calcium resinate (limed rosin).
Zinc rosinate.

(6) Phenolic resins by reaction of formaldehyde with:

Alkylated phenols (methyl, ethyl, propyl, isopropyl, butyl).
Bisphenol.
Ortho-, meta-, and paracresol
Paracyclohexyl phenol.
Paranonyl phenol.
Paraoctyl phenol.
Paraphenyl phenol.
Paratertiary amylphenol.
Paratertiary butylphenol.
Phenol.
Xylenol.

(7) Polyester resins (including alkyd type) formed as ester of acids in subdivisions (i) and (ii) of this subparagraph, by reaction with polyhydric alcohols in subdivision (iii) of this subparagraph:

(i) Polybasic acids:

Adipic.
Dimerized fatty acids derived from oils listed in subparagraph (1) of this paragraph.
Fumaric.
Isophthalic.
Maleic.
Orthophthalic.
Rosin-maleic acid adduct (petrex acid).
Sebacic.
Terephthalic.
Trimellitic.

(ii) Monobasic acids:

Benzoic.
Fatty acids derived from oils listed in subparagraph (1) of this paragraph.
Rosins and rosin acids (see subparagraph (5) of this paragraph).
Tertiary butyl benzoic.

(iii) Polyhydric alcohol:

Glycerol.
Mannitol.
α-Methyl glucoside.
Pentaerythritol.
Propylene glycol.
Sorbitol.
Trimethylol ethane.
Trimethylol propane.

(8) Epoxy resins:

Bisphenol-epichlorohydrin.
Bisphenol-epicholorhydrin reacted with drying oils or fatty acids listed in subparagraph (1) of this paragraph.
Bisphenol-epichlorohydrin combined with:
Bisphenol-formaldehyde.
Diethylene triamine.
Melamine-formaldehyde.
Phenol-formaldehyde.
Urea formaldehyde.

(9) Coumarone-indene resin.
(10) Petroleum hydrocarbon resin.
(11) Terpene.
(12) Urea-formaldehyde.
(13) Triazine-formaldehyde resins:

Benzoguanamine.
Melamine.

(14) Modifiers (for oils and alkyds, including polyesters):

Butyl methacrylate.
Cyclopentadiene.
Diallyl phthalate.
Methyl methacrylate.
Styrene.
Vinyl toluene.

(15) Vinyl resinous substances:

Polyvinyl acetate.
Polyvinyl alcohol (for fatty foods only).
Polyvinyl butyral.
Polyvinyl chloride.
Polyvinyl formal.
Polyvinylidene chloride.
Polyvinyl pyrrolidone.
Polyvinyl stearate.
Vinyl chloride-acetate-copolymer.
Vinyl chloride-acetate, hydroxyl modified-copolymer.
Vinyl chloride-acetate, maleic acid modified-copolymer.
Vinyl chloride-acrylonitrile-copolymer.
Vinyl chloride-maleic ester-copolymer.
Vinyl chloride-vinylidene chloride-copolymer.

(16) Cellulosics:

Carboxymethylcellulose.
Cellulose acetate.
Cellulose acetate-butyrate.
Cellulose acetate-propionate.
Ethylcellulose.
Ethyl hydroxy ethylcellulose.
Hydroxy propyl methylcellulose.
Methylcellulose.
Nitrocellulose.

(17) Styrene polymers:

Polystyrene.
Polymethyl styrene.
Styrene-acrylonitrile copolymer.

(18) Polyethylene (branched and linear)

(19) Polypropylene.

(20) Acrylics and their copolymers:

Polybutyl methacrylate.
Polyethyl acrylate.
Polyethyl methacrylate.
Polymethyl acrylate.
Polymethyl methacrylate.

(21) Elastomers:

Butadiene-acrylonitrile copolymer.
Butadiene-acrylonitrile-styrene copolymer.
Butadiene-styrene copolymer.
Butyl rubber.
2-Chloro-1,3-butadiene (neoprene) (with acceptable stabilizer and/or antiovidant).
Polyisobutylene (for nonfatty foods only).
Rubber hydrochloride.
Styrene-isobutylene copolymer.

(22) Driers made by reaction of a metal from subdivision (i) of this subparagraph with acid, to form the salt listed in subdivision (ii) of this subparagraph:

(i) Metals:

Calcium.
Cobalt.
Iron.
Magnesium.
Manganese.
Zinc.
Zirconium.

(ii) Salt:

Caprylate.
Linoleate.
Naphthenate.
Octoate (2-ethylhexoate).
Oleate.
Palmitate.
Resinate.
Ricinoleate.
Soyate.
Stearate.
Tallate.

(23) Waxes:

Microcrystalline, and paraffin:

Type I: A congealing point of 160° F. maximum (ASTM D-938), an absorptivity at 290 millimicrons of 0.04 liter per gram centimeter maximum (ASTM E-131), an oil content of 1.5 percent maximum (ASTM D-721), and a Saybolt color of 20 minimum (ASTM D-156).

Type II: Absorptivity at 290 millimicrons of 1.0 maximum, an oil content of 5.0 percent maximum, and a color of 3.0 maximum (ASTM D-1500).

Montan.
Polyethylene.
Sperm oil.
Spermaceti.

(24) Plasticizers:

(i) Chemical type:

Acetyl tributyl citrate.
Acetyl triethyl citrate.
Aluminum mono-, di-, and tristearate.
Butyl stearate.
Butyl phthalyl butyl glycolate.
p-tert. Butyl phenyl salicylate.
Dibutyl sebacate.
di-2-Ethyl hexyl phthalate.
Diethyl phthalate.
Dioctyl sebacate.
Ethyl phthalyl ethyl glycolate.
2-Ethylhexyl diphenyl phosphate.
Glycerol.
Glyceryl monooleate.
Glyceryl triacetate.
di-Isobutyl adipate.
di-Isooctyl phthalate.
mono-Isopropyl citrate.
Propylene glycol.
Sorbitol.
Triethyl citrate.
mono-, di-, and Tristearyl citrate.

(ii) Epoxy type:

Epoxidized soybean oil (iodine number less than 6; oxirane oxygen content 6% minimum).
3(2-Xenoxyl)-1,2-epoxypropane.

(25) Release agents:

Linoleic acid amide.
Oleic acid amide.
Palmitric acid amide.
Petrolatum.
Polyethylene glycol 400, 1,500, and 4,000.
Polyethylene wax.
Polytetrafluoroethylene.
Silicones(not less than 300 centistokes).
Stearic acid amide.
Waxes, microcrystalline and paraffin, complying with the specifications set out in paragraph (23) of this paragraph.

(26) Pigments and colorants:

Aluminum.
Aluminum hydrate.
Aluminum and potassium silicate (mica).
Aluminum mono-, di-, tristearate.
Aluminum silicate (china clay).
Barium sulfate.
Bentonite.
Bentonite, organic-base modified.
Burnt umber.
Calcium carbonate.
Calcium silicate.
Calcium sulfate.
Carbon black ("cannel" process).
Iron oxides.
Magnesium oxide.
Magnesium silicate (talc).
Raw sienna.
Silica.
Tartrazine lake (certified FDC Yellow No. 5 only).
Titanium dioxide.
Titanium dioxide-barium sulfate (approximately 70%-30% ratio).
Titanium dioxide-calcium sulfate (approximately 70%-30% ratio).
Titanium dioxide-magnesium silicate (approximately 70%-30% ratio).
Zinc oxide.

(27) Miscellaneous materials:

Ammonium citrate.
Ammonium potassium phosphate.
Calcium acetate.
Calcium ethyl acetoacetate.
Calcium glycerophosphate.
Calcium, sodium, and potassium oleates.
Calcium, sodium, and potassium ricinoleates.
Calcium, sodium, and potassium stearates.
Disodium hydrogen phosphate.
Lecithin (edible grade).
Magnesium, sodium, and potassium citrates.
Magnesium glycerophosphate.
Magnesium stearate.
Mono-dibutyl amine pyrophosphate.
Mono-, di-, and tricalcium phosphate.
Mono-, di-, and trimagnesium phosphate.
Phosphoric acid.
Sodium pyrophosphate.
Sodium tetrapyrophosphate.
Tin stearate.

(28) Surface lubricants:

Cottonseed oil and other edible oils.
Dibutyl sebacate.
Dioctyl sebacate.
Glyceryl monostearate.
Palm oil.
Paraffin wax complying with the specifications set out in subparagraph (23) of this paragraph.
Petrolatum.
Stearic acid.
White (mineral) oil.

The original request to extend the effective date of the statute for food additives that may migrate from linings of containers used in food packaging included maleic acid adducts, bisphenol-epichlorohydrin combined with allyl ether of mixed methylol phenols, bisphenol-epichlorohydrin combined with reactive polyamides, mixed acrylates, chlorinated rubber, diethylene glycol, ethylene glycol and silicones (not less than 300 centistokes viscosity). These additives are not included in this regulation extending the effective date of the statute, pending the evaluation of additional data that will specifically identify the particular substance for which the extension is requested.

Notice and public procedure are not necessary prerequisites to the promulgation of this order, and I so find, since extensions of time, under certain conditions, for the effective date of the food additives amendment to the Federal Food, Drug, and Cosmetic Act were contemplated by the statute as a relief of restrictions on the food-processing industry.

Effective date. This order shall be effective as of the date of signature.

(Sec. 701, 52, Stat. 1055, as amended; 21 U.S.C. 371. Interprets or applies 72 Stat. 1786; 21 U.S.C., note under sec. 342)

Dated: March 9, 1960.

[SEAL] GEO. P. LARRICK,
Commissioner of Food and Drugs.

[F.R. Doc. 60-2344; Filed, Mar. 16, 1960; 8:45 a.m.]